DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 3, 2014

ArtVentive Medical Group, Inc.
% Roberta Hines
Northwest Clinical Research Group, Inc.
24125 85th Avenue SE
Woodinville, WA 98072

Re: K133924
Trade/Device Name: Endoluminal Occlusion System (EOS)™
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 22, 2014
Received: October 24, 2014

Dear Roberta Hines:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133924

Device Name
Endoluminal Occlusion System (EOS)™

Indications for Use *(Describe)*
The ArtVentive Medical Group Endoluminal Occlusion System (AVMG EOS) is indicated for the percutaneous occlusion of the peripheral arterial and venous vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K133924

510(k) Summary

In accordance with 21 CFR 807.92 (Summary):

A summary of the information regarding the safety and effectiveness of the ArtVentive Medical Group Endoluminal Occlusion System (AVMG EOS™), as required by the Safe Medical Device Amendments of 1990, is provided as follows:

510(k) Summary for the
ArtVentive Medical Group Endoluminal Occlusion System™

1. Applicant:	ArtVentive Medical Group, Inc.
2. Address:	ArtVentive Medical Group, Inc. 2766 Gateway Road Carlsbad, CA 92009
3. Sponsor Contact Person:	Leon Rudakov, PhD., President and CTO
4. Telephone: **E-mail:**	650-465-5259 leonrudakov@artventivemedical.com
5. 510(k) Summary Preparation Date:	December 2, 2014
6. Device Trade Name:	Endoluminal Occlusion System (EOS)™
7. Common Name:	Vascular Embolization Device
8. Classification Name:	Device Embolization, Vascular (21 CFR 870.3300, Product Code: KRD)
9. Legally Marketed Predicate Devices:	AGA Medical/Amplatzer® Vascular Plug II (K071125) AGA Medical/Amplatzer® Vascular Plug 4 (K113658) Reverse Medical MVP™ Micro Vascular Plug System (K123803)

10. Description of the ArtVentive Medical Group - Endoluminal Occlusion System (EOS™):

The ArtVentive Medical Group Endoluminal Occlusion System™ (AVMG EOS™) has been developed for arterial and venous embolizations in the peripheral vasculature. The system consists of three major components: a preloaded implant, the implant carrier catheter, and the guide sheath with removable core. The AVMG EOS™ is intended for single use only.

The implant is made of a Nitinol coil scaffold with an ePTFE occlusion membrane and is designed with radial force sufficient to provide stiffness and strength against the vessel wall and minimize post-deployment migration. The delivery system is made up of the implant carrier catheter and the guide sheath with removable core. The implant carrier catheter contains one implant loaded on the distal end and a deployment handle on the proximal end connected by the shaft. The delivery catheter has a low profile and is flexible to allow for trackability and pushability. The implant itself and catheter's distal end are visible under fluoroscopy.

The guide sheath is a braided shaft with a stiff proximal section and a more flexible distal section to enable tracking through tortuous peripheral vasculature. A radiopaque marker on the distal end of the sheath is visible under fluoroscopy. The tip of the sheath is tapered to fit over the removable core. The removable core fits inside the guide sheath, exiting out through the distal end. The removable core also has a tapered end for ease of advancement into the blood vessel. The guidewire and core are removed from the guide sheath once it is in position for delivery of the implant.

11. Comparison to Predicate Devices:

Manufacturer / Device	**ArtVentive Medical Group, Inc./EOS**	**AGA Medical / Amplatzer® Vascular Plug II**	**AGA Medical / Amplatzer® Vascular Plug 4**	**Reverse Medical MVP™ Micro Vascular Plug System**
510(k) Number	K133924	K071125	K113658	K123803
Application / Product Code	21 CFR 870.3300 (KRD)	21 CFR 870.3300 (KRD)	21 CFR 870.3300 (KRD)	21 CFR 870.3300 (KRD)
FDA Classification	Class II	Class II	Class II	Class II
Technological Characteristics				
Intended Use	The ArtVentive EOS™ is intended for arterial and venous embolizations in the peripheral vasculature.	The AMPLATZER® Vascular Plug II is indicated for arterial and venous embolizations in the peripheral vasculature.	The AMPLATZER Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature.	The Reverse Medical MVP™ Micro Vascular Plug System is intended for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.
Design Features	Flexible, low profile device for immediate, acute occlusion of the target vessel. The device incorporates an ePTFE cover. Retrievable; may be removed during deployment and re-positioned. Two-stage deployment handle on the proximal end. The catheter has a stiff proximal section for pushability and a flexible distal section for trackability. The deployment handle has a side port to accommodate syringe attachment to flush the catheter of air and to pre-expand the ePTFE membrane before deploying the implant.	Unique multi-segmented, multi-layered design significantly reduces occlusion time for transcatheter embolization procedures. The three adjustable lobes of the AMPLATZER Vascular Plug II are designed for enhanced conformability to vessel landing zones. May be repositioned. Multiple vascular plugs may be used to occlude vessel.	The AMPLATZER® Vascular Plug 4 is delivered through a 0.038 diagnostic catheter. The flexible mesh and the floppy distal section of the delivery wire enable the device to travel through tortuous anatomy with ease while the multi-layered, double-lobed design provides rapid embolization. May be repositioned.	The MVP Device is ovoid-shape, comprised of nitinol and secured at both ends with platinum marker bands. The device incorporates a PTFE partial cover. The proximal marker band attaches to a wire that pushes the device through a commercially available microcatheter to the intended treatment site. The "delivery wire" detaches from the MVP Device by electrolytic means after deployment with the Reverse Medical Detachment System. Full resheathability enables precise delivery. The MVP System is packaged as a single unit with the MVP Device, introducer sheath and detachable delivery wire. The system is provided sterile, non-pyrogenic, and is intended for single use only.
Material	Nitinol coil with an ePTFE polymeric cover	Nitinol mesh	Nitinol mesh with a radiopaque marker band	Nitinol coil with an ePTFE polymeric partial cover and platinum marker bands
Detachment	Mechanical in nature	Mechanical in nature	Mechanical in nature	Electrolytic means of deployment

Manufacturer / Device	ArtVentive Medical Group, Inc./EOS	AGA Medical / Amplatzer® Vascular Plug II	AGA Medical / Amplatzer® Vascular Plug 4	Reverse Medical MVP™ Micro Vascular Plug System
Sizes	Diameter (mm) Length (mm) 5 11 8 20 5mm diameter for target vessel diameter 3.0mm – 5.0mm 8mm diameter for target vessel diameter 4.5mm – 8.0mm)	Diameter (mm) Length (mm) 3 6 4 6 6 6 8 7 10 7 12 9 14 10 16 12 18 14 20 16 22 18	Diameter (mm) Length (mm) 4 10.0 5 10.5 6 11.0 7 12.5 8 13.5	Diameter (mm) Length (mm) 5.3 12 6.5 12 5.3 mm diameter used for target vessel diameter 1.5-3.0 mm 6.5 diameter used for target vessel diameter 3.0-5.0 mm
Treatment Method	Permanent Implant	Permanent Implant	Permanent Implant	Permanent Implant
How Applied	Via catheter through guide sheath to target vessel	Via guiding catheter to the target vessel	Via guiding catheter to the target vessel	Via catheter through guide sheath to target vessel

12. Intended use of the ArtVentive Medical Group - Endoluminal Occlusion System (EOS)™:

The ArtVentive Medical Group Endoluminal Occlusion System™ (AVMG EOS™) is indicated for arterial and venous embolizations in the peripheral vasculature.

13. Performance Data:

Bench studies indicate that the ArtVentive Medical Group's EOS™ device performs as intended. The following testing was performed: dimensional and functional design verification/validation, sterilization validation, transit and package integrity testing, shelf life testing, GLP chronic animal safety testing, MRI compatibility, corrosion, radial strength and biocompatibility testing.

14. Substantial Equivalence:

The performance of the ArtVentive EOS demonstrates that the product is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specifications, performance, biocompatibility testing, animal testing, and sterilization validation. The AVMG EOS is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the predicate devices. Differences between the devices do not raise any significant issues of safety or effectiveness.